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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/681,878	10/09/2003	Vincent L. Chiang	50617.C1/C-3532.0	8100
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EXAMINER

BAUM, STUART F

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 01/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/681,878	<b>Applicant(s)</b> CHIANG ET AL.	
	<b>Examiner</b> Stuart F. Baum	<b>Art Unit</b> 1638	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 1-26, 28 and 30-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27 and 29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/9/2003</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Claims 1-45 are pending.
2. Applicant's election with traverse of Group VIII, claims 27 and 29 in the reply filed on 11/10/2005 is acknowledged. The traversal is on the ground(s) that "the evidence and explanation do not establish a serious burden" (page 3 of Remarks, 2<sup>nd</sup> paragraph).

This is not found persuasive because while the search of the prior art for one group may overlap with that of another, they are not co-extensive of each other and thus would be a burden on the Office.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-26, 28, and 30-45 are withdrawn from consideration for being drawn to non-elected inventions.

3. Claims 27 and 29 including SEQ ID NO:6 are examined in the present office action.

### ***Specification***

4. Objection is made to the specification for not incorporating SEQ ID NO's when referring to nucleic acid or amino acid sequences. 37 CFR 1.821(d) requires the use of the assigned sequence identifier (e.g. SEQ I.D. NO: X) in all instances where the description or claims of a patent application discuss sequences. See for example page 10, lines 32 and 34; page 11; page 12, lines 28-30; page 14; and page 17, lines 10-11. In addition, each of Figures 2-8 disclose both DNA and amino acid sequences but the Brief Description of the Drawings only disclose one sequence identifier, which the Office notes, is not the same sequence number as is indicated on each of the figures. Correction is requested.

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The specification is objected to for the inclusion of a blank on page 17, line 33.

***Drawings***

5. Figure 9 is objected to because the image is too dark and no discernable data can be observed. Correction is requested.

***Brief Description of the Drawings***

6. The Specification is objected to because the drawings are not referred to properly. If the drawings show Figures 2A-2E, then the Brief Description of the Drawings should recite "Figures 2A-2E", instead of "Figure 2". Correction is requested.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 is indefinite for reciting an isolated DNA sequence.... as shown in SEQ ID NO:6. The computer readable form (CRF) of Applicants' SEQ ID NO:6 is an amino acid sequence comprising 368 amino acids. Applicants' SEQ ID NO:6 as listed on pages 35-36 of the instant specification is a DNA sequence comprising 659 nucleotides. Applicants have indicated that the sequence listing in the present case is identical to the sequence listing from U.S. patent

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6,252,135, whose application is 09/991,677 (see Applicants' response filed 4/12/2004). In the '135 patent, SEQ ID NO:6 is an amino acid sequence. It is unclear to what Applicant is referring in claim 27, by the recitation "SEQ ID NO:6".

***Written Description***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 27 and 29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an isolated DNA sequence which includes the 5' flanking region of the gymnosperm loblolly pine 4CL1B, containing the lignin promoter region and regulatory elements for gymnosperm lignin biosynthesis as shown in SEQ ID NO:6 and to an isolated DNA which includes the promoter region of a gymnosperm gene involved in syringyl lignin biosynthesis.

Because of the 112 second paragraph indefiniteness issue concerning "an isolated DNA sequence.... as shown in SEQ ID NO:6" as discussed above, the Office interprets the claim to read on any loblolly pine 4CL1B 5' flanking region.

Because Applicants have not specifically defined "a gymnosperm gene involved in syringyl lignin biosynthesis", the Office broadly interprets this to mean any gene that in any way

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contributes to the synthesis of syringyl lignin in a plant cell, which reads on a great number of sequences.

Applicants disclose the isolation of a promoter fragment from the 4CL1B gene of loblolly pine was isolated using a Universal GenomeWalker™ kit (page 15, 5<sup>th</sup> paragraph). Applicants disclose a nucleotide sequence of the 5' flanking region of the loblolly pine 4CL1B gene in Figure 6, which Applicants label as SEQ ID NO:6 in the brief description of the drawings but which is labeled as SEQ ID NO:10 in the figure (page 3, Fig. 6 legend; and page 28 of drawings).

The Applicants do not identify essential regions of the promoter of any loblolly pine 4CL1B gene nor any promoter region of any gymnosperm gene involved in syringyl lignin biosynthesis.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the

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genus.” See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of polynucleotide promoter sequences falling within the scope of the claimed genus of polynucleotides which comprise the 5' flanking region of any loblolly pine 4CL1B gene or any promoter region of any gene that in any way contributes to the synthesis of syringyl lignin. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for the promoter sequence from either the 4CL1B gene from loblolly pine or from any gene involved in syringyl lignin biosynthesis, it remains unclear what features identify a loblolly pine 4CL1B 5' flanking region or what features identify the promoter region from any gene involved in syringyl lignin biosynthesis, as broadly interpreted by the office, as discussed above. Since the genus of said sequences has not been described by specific structural features, the specification fails to provide an adequate written description to support the breadth of the claims.

### ***Enablement***

9. Claims 27 and 29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to an isolated DNA sequence which includes the 5' flanking region of the gymnosperm loblolly pine 4CL1B, containing the lignin promoter region and regulatory elements for gymnosperm lignin biosynthesis as shown in SEQ ID NO:6 and to an isolated DNA which includes the promoter region of a gymnosperm gene involved in syringyl lignin biosynthesis.

Because of the 112 second paragraph indefiniteness issue concerning "an isolated DNA sequence... as shown in SEQ ID NO:6" as discussed above, the Office interprets the claim to read on any loblolly pine 4CL1B 5' flanking region.

Because Applicants have not specifically defined "a gymnosperm gene involved in syringyl lignin biosynthesis", the Office broadly interprets this to mean any gene that in any way contributes to the synthesis of syringyl lignin in a plant cell, which reads on a great number of sequences.

Applicants disclose the isolation of a promoter fragment from the 4CL1B gene of loblolly pine was isolated using a Universal GenomeWalker™ kit (page 15, 5<sup>th</sup> paragraph). Applicants



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disclose a nucleotide sequence of the 5' flanking region of the loblolly pine 4CL1B gene in Figure 6, which Applicants label as SEQ ID NO:6 in the Brief Description of the Drawings but which is labeled as SEQ ID NO:10 in the figure (page 3, Fig. 6 legend; and page 28 of drawings).

Benfey et al (1990, Science 250:959-966) teach that the 35S CaMV promoter consists of domains that individually regulate spatial expression within plants. "The combination of each of the five B subdomains with domain A results in an expression pattern that differs from that of the individual subdomains or domain A" (page 961, left column, 2<sup>nd</sup> paragraph). In other words, deleting a required domain will jeopardize the proper spatial and temporal expression pattern. In addition, Benfey et al (1989, EMBO J, 8(8):2195-2202; page 2200, left column 2<sup>nd</sup> paragraph) teach that not only are the promoter domains important for specifying proper spatial and temporal expression but that when all domains were present, the quantity of expression increased.

Applicants have not disclosed how one makes or isolates any of the sequences that are encompassed by Applicants' broad claims. Applicants have not taught which regions of the respective polynucleotides can be used to amplify any of said polynucleotides or which regions can be used as a probe to isolate any of said polynucleotide sequences.

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified sequences, either by using non-disclosed fragments of any region of any 4CL1B gene from loblolly pine or from any promoter from any gene involved in syringyl lignin biosynthesis as probes or by designing primers to undisclosed regions of said fragments and isolating or amplifying

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fragments, subcloning the fragments, producing expression vectors and transforming plants therewith, in order to identify those, if any, that have promoter activity, though Applicants have not disclosed the specific spatial and temporal expression profile that is to be used as a reference.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claim 29 is rejected under 35 U.S.C. 102(b) as being anticipated by Kojima et al (1994, The Plant Journal 6(4):591-596).

The claim is drawn to an isolated DNA which includes the promoter region of a gymnosperm gene involved in syringyl lignin biosynthesis.

Because Applicants have not specifically defined “a gymnosperm gene involved in syringyl lignin biosynthesis”, the Office broadly interprets this to mean any gene that in any way contributes to the synthesis of syringyl lignin in a plant cell, which reads on a great number of sequences.

Kojima et al disclose a chimeric gene consisting of the pine cab-6 promoter. The Office considers the cab-6 gene to be involved in syringyl lignin biosynthesis because the cab-6 gene is involved in photosynthesis which is required by the plant to synthesize precursors of syringyl lignin and to produce ATP which is also required by the plant to produce syringyl lignin, and as such, Kojima et al anticipate the claimed invention.

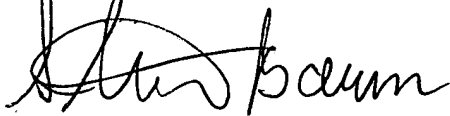
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11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

A handwritten signature in black ink, appearing to read 'Stuart F. Baum', is written over the printed name.

Stuart F. Baum Ph.D.

Patent Examiner

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January 20, 2006